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(11) **EP 1 060 757 A1**

(12)

EUROPEAN PATENT APPLICATION

(43) Date of publication:
20.12.2000 Bulletin 2000/51

(51) Int Cl.⁷: **A61M 25/00, F16L 3/223,
F16L 3/237**

(21) Application number: **00650055.7**

(22) Date of filing: **19.05.2000**

(84) Designated Contracting States:
**AT BE CH CY DE DK ES FI FR GB GR IE IT LI LU
MC NL PT SE**
Designated Extension States:
AL LT LV MK RO SI

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(30) Priority: **19.05.1999 US 314706**

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(54) **A coiling clip for a catheter guide wire**

(57) The invention provides a coiling clip (1) for a catheter guide wire dispenser tube (8), the coiling clip having two side-by-side resilient C-shaped sockets (3) having longitudinal slit-like socket mouths (4) for reception of the tube (8). Each socket (3) has a bearing sur-

face (5) which carries a plurality of upstanding tube engaging protuberances (6) formed by parallel ribs (7). Other types of protuberance may be used and indeed coiling clips with sockets having their socket mouths offset from each other around the clip may be provided.

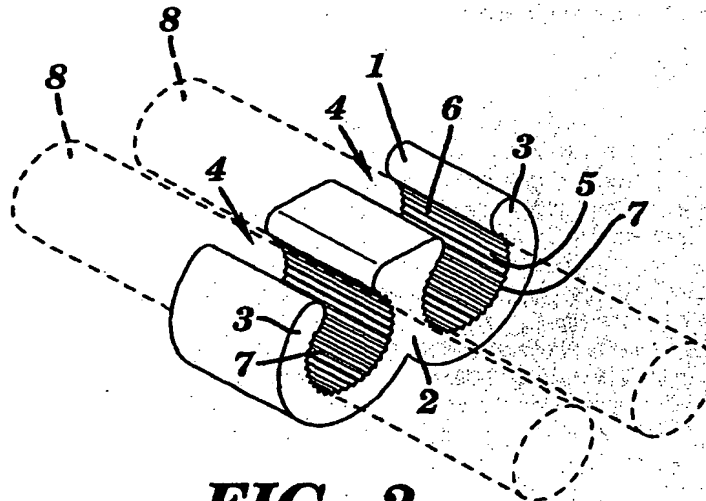


FIG. 2

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Description**Introduction**

5 [0001] There are many medical procedures where catheters are used. Frequently, other apparatus is used with the catheter. For example, when a catheter is introduced into a patient's blood vessel such as an artery or vein, guide wires are routinely used.

[0002] In a typical procedure, one uses the guide wires for the positioning of a catheter. For instances, in the Seldinger technique, a catheter introducer is used which has a relatively short flexible cannula which is placed within the patient's blood vessel. Actual insertion of the cannula is assisted by the use of a needle which is positioned within the cannula and is thus inserted into the blood vessel. Upon insertion, the needle is withdrawn, leaving the cannula tip within the blood vessel while the body of the catheter introducer remains external of the patient.

10 [0003] A guide wire is then inserted through the catheter introducer and is extended through the tip of the cannula within the patient's blood vessel until it is positioned with its tip at the desired location within the patient. Upon removal of the catheter introducer, the guide wire remains in the patient and a long catheter is easily slid over the guide wire to the desired position and the guide wire withdrawn. Thus, the catheter remains within the patient having its distal end located at the proper position within the patient's blood vessel.

[0004] These catheters can be used for a variety of medical techniques including angioplasty, gene delivery, etc. Thus, the guide wires, once introduced into the body, can extend to distant sites.

20 [0005] Anytime any object is introduced into the blood stream, care must be taken to ensure that sterility is maintained and that the object used does not cause infection. One method by which this goal has been met is the trend to single use devices which are sterilised when made, then shipped and ready to use.

[0006] Such guide wires are delivered through normal shipping channels and are subject to considerable handling prior to and during shipment. The guide wire itself is packaged within a dispenser or protective tube in a coiled form referred to as a "spiral wound" dispenser. A typical guide wire introducer is disclosed in U.S. Patent No. 5,282,479.

25 [0007] Presently, several clips or retainers referred to as "coiling clips" are used to anchor the coiled tube. These are devices having a smooth inner surface which hold the tube by exerting pressure against the tube wall. Such a coiling clip comprises at least two side-by-side C-shaped sockets having longitudinal slit-like socket mouths for reception of the tube. However, during transport, it is common for a segment of the tube to "pop out" of the clip. Thus, before using the device, the physician must waste valuable time inserting the tube back into the clip. Such additional handling can not only waste time, but may compromise the sterility. This can also cause a serious problem for the physician if, when using the dispenser, a portion of the tube pops out of the clip. Accordingly, there is a need for a coiling clip that more securely anchors the spiral wound dispenser.

35 **Statements of Invention**

[0008] According to the invention, there is provided a coiling clip for a catheter guide wire dispenser tube, the coiling clip comprising at least two side-by-side resilient C-shaped sockets having longitudinal slit-like socket mouths for reception of the tube, each socket having a tube supporting and contacting internal bearing surface characterized in that each bearing surface includes a plurality of upstanding tube engaging protuberances dimensioned such as to cause a force-fit of the tube within the socket.

40 [0009] The protuberances may comprise longitudinally arranged parallel striations or ribs or may be semi-spherical protuberances. The socket mouths may be arranged in any general configurations around the clip such as in side-to-side relationship or offset around the clip.

45 [0010] Ideally, the coiling clip is of a plastics material.

[0011] Further, there is provided according to the invention a guide wire assembly comprising a coiling clip as described above and a dispenser tube wound thereon.

[0012] Ideally, the dispenser tube houses a catheter wire wound therein in which the dispenser tube has a plurality of longitudinal grooves for interengagement with the protuberance forming ribs.

50 [0013] Preferably, the coiling clip is of a harder material than that of the dispenser tube such that the coiling clip protuberances form indentations in the dispenser tube.

[0014] According to the invention, there is provided a method of forming a guide wire assembly comprising:-

55 taking a plurality of clips;

inserting the tube into the socket mouth of one or more of the clips;

rotating the turntable while progressive feeding the tube into the clips thus winding the tube into a coil of the desired

size; and

continuing to insert the tube into the clips until the assembly is formed.

[0015] It will be appreciated that the method comprises forming the assembly of a number of windings of the tube, the tube being inserted into the clip for each winding of the tube.

Detailed Description of the Invention

[0016] The invention will be more clearly understood from the following description of some embodiments thereof, given by way of example only, with reference to the accompanying drawings, in which:-

Fig. 1 is a perspective view of a coiling clip of the present invention,

Fig. 2 is a perspective view of the coiling clip of Fig. 1 engaging a dispenser tube,

Fig. 3 is a perspective view of a guide wire assembly incorporating some of the coiling clips of Fig. 1,

Fig. 4 is a perspective view of an alternative construction of dispenser tube engaging the coiling clip of Fig. 1,

Fig. 5 is a sectional view along the lines V-V of Fig. 4,

Fig. 6 is a perspective view of another construction of coiling clip according to the invention,

Fig. 7 is a perspective view of a further construction of coiling clip,

Fig. 8 is a perspective view of another coiling clip, and

Fig. 9 is a perspective view of a further coiling clip according to the invention.

[0017] Referring to the drawings and initially to Figs. 1 to 3 thereof, there is provided a coiling clip, indicated generally by the reference numeral 1, having a body 2 mounting two side-by-side resilient C-shaped sockets 3, each having a longitudinal slit-like socket mouth 4. Each socket 3 has a tube supporting and contacting internal bearing surface 5 for reception of a dispenser tube. The bearing surface 5 carries a number of protuberances 6, in this embodiment formed by longitudinally arranged parallel striations or ribs 7.

[0018] Referring now to Fig. 2, there is illustrated, by interrupted lines, portion of a dispenser tube 8 mounted in the coiling clip 1.

[0019] Referring now specifically to Fig. 3, to form a guide wire assembly 10 from a coiling clip 1 and a dispenser tube 8 which dispenser tube 8 houses a catheter wire, the coiling clip 1 is taken and the dispenser tube 8 is inserted into the clip 1. Then, the dispenser tube 8 is wound into a coil of the desired size and again, the dispenser tube 8 is inserted in the clip 1 to form and hold the coil in position. Then, additional clips 1 are used and the dispenser tube 8 is inserted into them to provide the guide wire assembly, indicated clearly in Fig. 3 and identified by the reference numeral 10. It will be noted that the guide wire assembly holds other clips, identified by the reference numeral 30, which have not yet been described but will be described later.

[0020] It has been found that a turntable is particularly suitable for the forming of the guide wire assembly 10. If a turntable is used, the turntable may be either a driven turntable or simply rotated by the operator's hands. If a turntable is used, then a number of clips 1 are placed on the turntable and then the tube 8 is inserted into one of the clips 1, the turntable is rotated slightly, the tube is inserted into the next clip on the turntable by pushing the tube 8 into the socket mouths of each clip. This is continued as the turntable is rotated thus progressively inserting the tube 8 into the socket mouths 4 of the clips 1. This causes the tube 8 to be wound into a coil of the desired size and when this is finished, the assembly 10 is formed. Generally, all that happens is that one keeps on winding or rotating the turntable and inserting the tube 8 into the clips until all the assembly is formed. In some embodiments, not necessarily all the clips will be immediately inserted onto the tube 8 as the coil is formed. Some may be inserted after the coil has been formed since all that is required from the clips is that there be sufficient clips on the turntable to retain the coil in position.

[0021] A test was carried out on the clip of Fig. 1. A four inch (10.16 cm) length of standard 0.152 inches (0.386 cm) tubing having a smooth outer surface was reinforced with a length of metal located on the inside of the tubing was provided. This tube was located on a looped chain at both ends. The chains were attached to a tensile force tester. The clip being tested was clamped to the bottom section of the tensile tester and the speed rate was set at 50 rpm.

The test was carried out against a standard clip of the prior art. The following results were obtained:

Sample No.	Existing Clip 51001	New Clip 51115
1	0.8 lbs	1.8 lbs
2	0.7 lbs	2.0 lbs
3	0.8 lbs	1.9 lbs
4	0.8 lbs	2.1 lbs
5	0.8 lbs	1.8 lbs
6	0.8 lbs	2.0 lbs
7	0.7 lbs	2.0 lbs
8	0.8 lbs	1.8 lbs
9	0.7 lbs	2.0 lbs
10	0.8 lbs	1.8 lbs

[0022] As can be seen there is a significantly greater resistance to movement and a much higher tensile value when removed from the clip. This clearly indicated that the clip according to the invention has considerably tighter grip than that of the prior art.

[0023] Referring now to Figs. 4 and 5, there is illustrated an alternative construction of dispenser tube, identified by the reference numeral 15, again mounted within a coiling clip 1. In this embodiment, the dispenser tube 15 has a plurality of longitudinally arranged grooves 16 for reception of the ribs 7. These grooves 16 ideally are complementary to the ribs 7 such that the ribs 7 and grooves 16 engage or mesh, in effect, locking the tube in position as can be clearly seen from Fig. 5.

[0024] Referring now to Fig. 6, there is illustrated a still further construction of coiling clip, indicated generally by the reference numeral 20, in which parts similar to those described with reference to the previous drawings are identified by the same reference numerals. In this embodiment, the bearing surface 5 has mounted thereon protuberances 25 of semi-spherical shape.

[0025] Referring to Fig. 7, there is illustrated an alternative construction of clip, indicated generally by the reference numeral 30, in which parts similar to those described with reference to Fig. 1 are identified by the same reference numerals. In this embodiment, there are three side-by-side sockets 3. These clips are used, as can be seen in Fig. 3, in forming the guide wire assembly 10. They are, in every respect, similar to the sockets 1 of Fig. 1.

[0026] Fig. 8 illustrates an alternative construction of socket, indicated generally by the reference numeral 35, and again parts similar to those described with reference to Fig. 1 are identified by the same reference numerals. In this embodiment, adjacent socket mouths 4 are offset by 180°.

[0027] Referring to Fig. 9, there is illustrated a still further construction of clip, indicated generally by the reference numeral 40. Again, parts similar to those described with reference to the previous drawings are identified by the same reference numerals. In this embodiment, there are four sockets 3, all of which have their socket mouth offset around the clip 40.

[0028] It is envisaged that the clips and dispenser tube according to the present invention will be manufactured from a suitable plastics material. Ideally, the coiling clips should be made from a suitable material which is resilient and flexible and will withstand all sterilisation methods. Such materials include High Density Polyethylene (HDPE), Low Density Polyethylene (LDPE), Polypropylene (PP), Poly Vinyl Chloride (PVC), Polycarbonate or any other Polyolefin material used for extrusion or injection moulding, including various blends. A particularly suitable material is one formed from approximately 60% HDPE and 40% LDPE blended together. The clip can be formed using an extrusion process or can be injection moulded. Extrusion is preferred.

[0029] It is envisaged that while the protective tube may be manufactured from a plastics material, that the coiling clip is manufactured from a stronger or harder plastics material such that the protuberances on the coiling clip will engage into the dispenser tube so as to further lock the dispenser tube into the coiling clip.

[0030] It will also be appreciated that textured surfaces, other than ribs or protuberances as shown, may be used as long as such a surface has the effect of forming a protuberance. Obviously, the dimensions of the clip have to be so formed as to provide a sufficient locking force onto the tube. Ideally, there is an inward pressure exerted by the coiling clip bearing surface on the outer surface of the tube. The idea of the invention is to ensure that the resilience of the clip, together with the projections, will be such as to lock the protective tube securely within the clip.

[0031] As has been shown by various tests, there has been a considerable increase in the resistance to pull out of a clip according to the present invention. Thus, there is less likely to be disassembly during transport.

[0032] Further it has been found that the clip slip has been reduced particularly when combined with the dispenser tube according to the invention. When clips slip they can cause difficulties when the assembly is inserted into certain

proprietary procedural trays.

[0033] In the specification the terms "comprise, comprises, comprised and comprising" or any variation thereof and the terms "include, includes, included and including" or any variation thereof are considered to be totally interchangeable and they should all be afforded the widest possible interpretation.

[0034] The invention is not limited to the embodiments hereinbefore described but may be varied in both construction and detail within the scope of the claims.

Claims

1. A coiling clip for a catheter guide wire dispenser tube, the coiling clip comprising at least two side-by-side resilient C-shaped sockets (3) having longitudinal slit-like socket mouths (4) for reception of the tube (8); each socket (1) having a tube supporting and contacting internal bearing surface (5) characterised in that each bearing surface (5) includes a plurality of upstanding tube engaging protuberances (6) dimensioned such as to cause a force-fit of the tube within the socket.
2. A coiling clip as claimed in claim 1, in which the protuberances (6) comprise longitudinally arranged parallel striations or ribs (7).
3. A coiling clip as claimed in claim 1 or 2, in which the protuberances (6) are substantially semi-spherical protuberances (25).
4. A coiling clip as claimed in any of claims 1 to 3, in which the socket mouths (4) are in side-by-side relationship.
5. A coiling clip as claimed in any of claims 1 to 3, in which adjacent socket mouths (4) are offset around the clip (40).
6. A coiling clip as claimed in any preceding claim, in which the coiling clip (1, 20, 30, 35, 40) is of a plastics material.
7. A guide wire assembly (10) comprising a coiling clip (1, 30) as claimed in any preceding claim, and a dispenser tube (8) wound thereon.
8. A guide wire assembly comprising a coiling clip (1, 30, 35, 40) as claimed in claim 2, and a dispenser tube (15) housing a catheter wire wound thereon in which the dispenser tube (15) has a plurality of longitudinal grooves (16) for interengagement with the protuberance forming ribs (7).
9. A guide wire assembly as claimed in claim 7 or 8, in which the coiling clip (1, 20, 30, 35, 40) is of a harder material than that of the dispenser tube (8, 15) such that the coiling clip protuberances form indentations in the dispenser tube.
10. A method of forming an assembly (10) as claimed in claims 7 to 9 comprising:-
 - taking a plurality of clips (1);
 - inserting the tube (8) into the socket mouth (4) of one or more of the clips (1);
 - rotating the turntable while progressive feeding the tube (8) into the clips (1) thus winding the tube (8) into a coil of the desired size; and
 - continuing to insert the tube (8) into the clips (1) until the assembly (10) is formed.
11. A method as claimed in claim 10, in which the method comprises forming the assembly (10) of a number of windings of the tube (8), the tube (8) being inserted into the clip (1) for each winding of the tube (8).

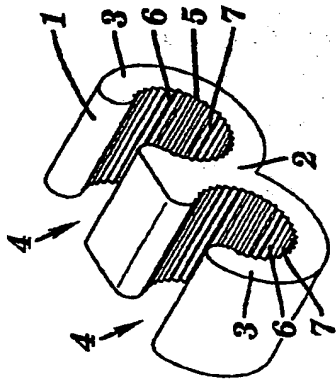


FIG. 1

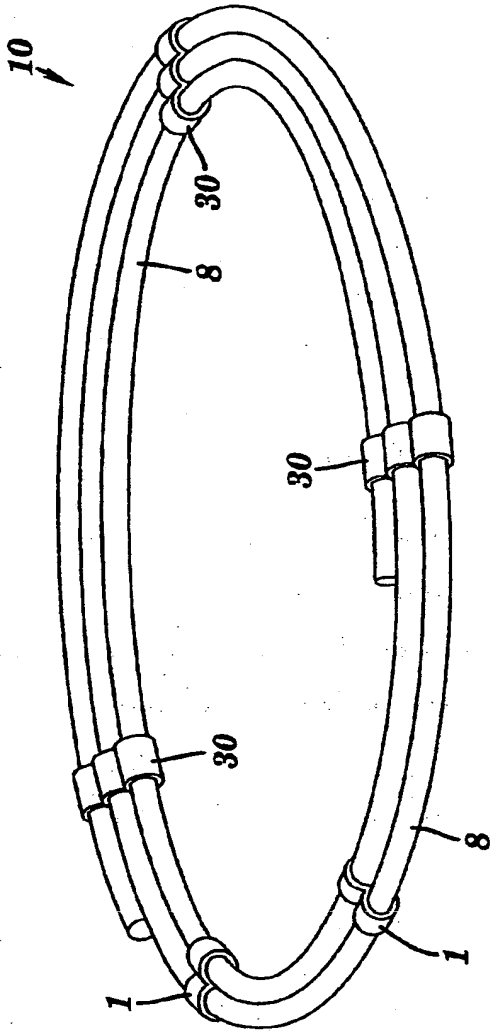


FIG. 3

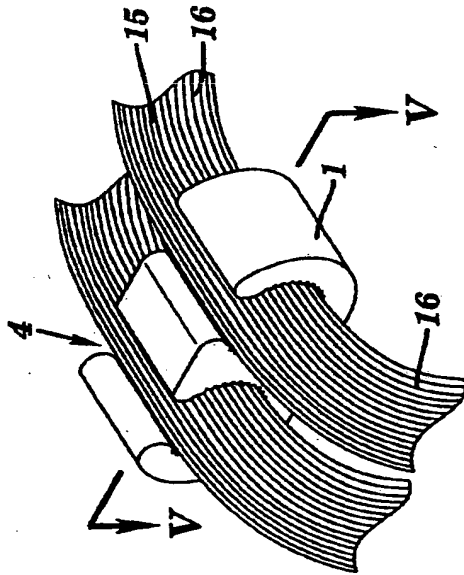


FIG. 4

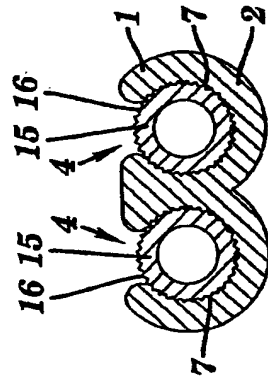


FIG. 5

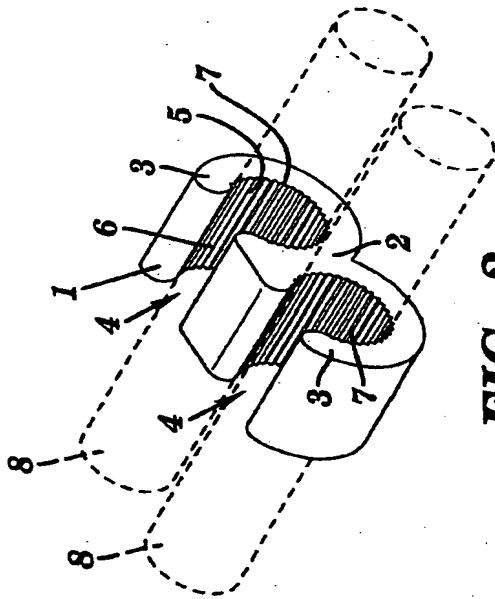


FIG. 2

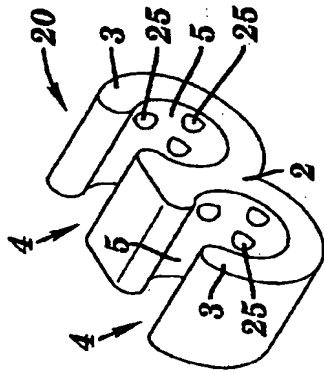


FIG. 6

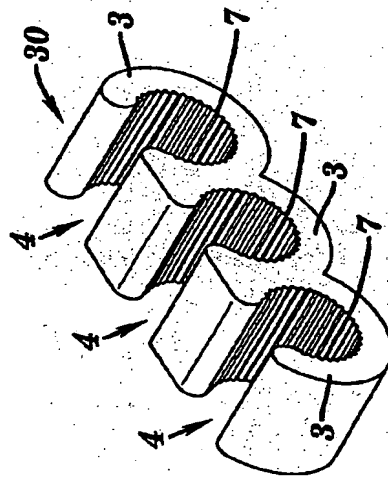


FIG. 7

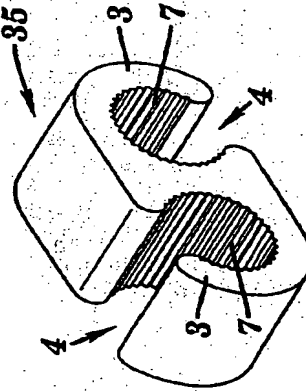


FIG. 8

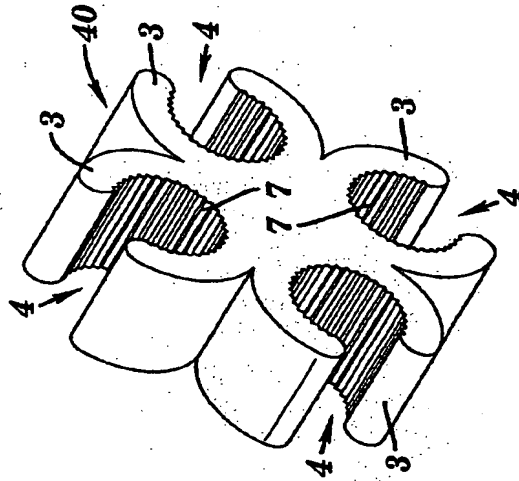


FIG. 9



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EUROPEAN SEARCH REPORT

Application Number
EP 00 65 0055

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The present search report has been drawn up for all claims			
Place of search THE HAGUE		Date of completion of the search 17 August 2000	Examiner Levert, C
<p>CATEGORY OF CITED DOCUMENTS</p> <p>X : particularly relevant if taken alone Y : particularly relevant if combined with another document of the same category A : technological background O : non-written disclosure P : intermediate document</p> <p>T : theory or principle underlying the invention E : earlier patent document, but published on, or after the filing date O : document cited in the application L : document cited for other reasons & : member of the same patent family, corresponding document</p>			

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**ANNEX TO THE EUROPEAN SEARCH REPORT
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